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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Atsushi Suzuki

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11/14/2008

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ALEXANDRIA, VA 22314

EXAMINER

UNDERDAHL, THANE E

ART UNIT

PAPER NUMBER

1651

NOTIFICATION DATE

DELIVERY MODE

11/14/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 09/922,694	Applicant(s) SUZUKI ET AL.	
	Examiner THANE UNDERDAHL	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-45,53-55,69 and 70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-45,53-55,69 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/15/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This Office Action is in response to the Applicant's reply received 3/3/08. Claims 40-45, 53-55, 69 and 70 are pending. No claims are withdrawn. Claims 46-52 and 56-68 are cancelled. No claims have been amended. No claims are new.

Reopening of Prosecution

In view of the appeal brief filed on 3/3/08, PROSECUTION IS HEREBY REOPENED. A new office action set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Michael G Wityshyn/
Supervisory Patent Examiner
Art Unit 1651

Response to Applicant's Arguments

In the response submitted by the Applicant the 35 U.S.C § 102 (b) rejection of claims 46 and 50 based on Abraham et al. is withdrawn in light of Applicant's

Art Unit: 1651

cancellation of these claims. The double patenting rejection of claims 40-42, 63-65, 69, and 70 over claims 1-11 of U.S. Patent # 6,310,100 in view of Yokozawa et al. is withdrawn in view of the terminal disclaimer filed 10/01/07. Also the 35 U.S.C § 103 (a) rejection of claims 46-52 and 63-65 based on Abraham et al. in view of Hsu, Ghai et al. and Yokozawa et al. is withdrawn in light of Applicant's cancellation of these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40, 41, 42, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saija et al. (J Sci Food Agric, 1999).

These claims are to a composition consisting of :

- a) Isolated or purified ferulic acid or an ester or pharmaceutically acceptable salt thereof, and
- b) Isolated or purified caffeic acid and/or chlorogenic acid or pharmaceutically acceptable salts thereof, and
- c) A suitable excipient or carrier

Wherein a) or b) are present in an amount sufficient to lower blood pressure or suppress a rise in blood pressure when administered to a mammal.

This composition can be prepared into various formulations including a tablet, pill, powder, drink, injection, or dermatological preparation. Claims 69 and 70 limit the mass of a) and b) in the composition. The Applicant is reminded that these claims are to a composition and as such are defined by their parts. Any limitation such as intended uses for the compositions such as suppressing "a rise in blood pressure in a mammal" (see claim 1) are given no patentable weight since it is the components of the composition that are the point of novelty and not their use.

Saija et al. teach that both caffeic or ferulic acid can each be formed into compositions with phosphate buffer as a carrier and applied to the skin surface as a dermatological preparation (pg 477, col 2, 2nd full paragraph down). After the appropriate conversions from a 0.200 mL solution Saija et al. teach that ferulic acid is present at 0.14 mg and caffeic acid at 0.084 mg. While Saija et al. does not teach a composition comprising both caffeic and ferulic acid together this would be obvious to one of ordinary skill in the art since they teach both acids are useful for the exact same purpose. M.P.E.P. § 2144.06 states

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art combine ferulic and caffeic acid in a single composition. Therefore this reference renders obvious claims 40, 41, 42, 69 and 70.

Claims 40-45 and 69, 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al.

Claims 43 and 44 limit the composition b) to a chlorogenic acid. Claim 44 limits the chlorogenic acid to a specific stereoisomer.

The descriptions of claims 40, 41, 42, 69 and 70 are recited in the previous 35 U.S.C § 103 rejection.

Huang et al. teach compositions comprising **TPA** (12-O-tetradecanoylphorbol-13-acetate) and either ferulic acid or caffeic acid or chlorogenic acid in a carrier of either acetone or acetone and DMSO (pg 5943, Table 1 and 2) and spread on the skin of mice (pg 5941, Abstract). The TPA is used as part of an assay to induce tumor formation and the ferulic, caffeic and chlorogenic acids are used to inhibit this TPA-induce tumor (pg 5941, Abstract). One of ordinary skill in the art would recognize that a pharmaceutical preparation of these acids would not have TPA and would consist only of the acid and carrier since inducing tumors would be counterproductive to therapy. Also since Huang et al. teach that chlorogenic acid, caffeic acid and ferulic acid are used for the same purpose it would be obvious to combine them into a composition consisting of all three. The support for this is found in M.P.E.P. § 2144.06, which states

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art combine ferulic, chlorogenic and caffeic acid in a single composition in the absence of evidence of criticality or unexpected results.

Also with the appropriate conversions of the amounts of the acids in the solutions in Tables 1 of Huang et al. provides the following results:

Compound	MW (g/mol)	Amount (umol)	Grams
Chlorogenic acid	354.31	10	0.0035
		20	0.0071
Caffeic acid	180.16	10	0.0018
		20	0.0036
Ferulic acid	194.184	10	0.0019
		20	0.0039
		50	0.0097

While these mass values meet the limitations of claim 69 they do not meet the limitations of claim 70. However the volume of the sample was only 0.2 mL (see Text of Table 1). Since both claim 69 and 70 limit that absolute amount of the acids in solution and not the concentration, if the volume of the sample was increased through routine optimization by one of ordinary skill in the art to cover the surface area treated then mass of acids in the composition would meet the limitations of claim 70 (M.P.E.P. § 2144.05 II).

Therefore this/these reference/s render/s obvious claims 40-45 and 69, 70.

Claims 40, 41, 42, 53-55, 69 and 70 rejected under 35 U.S.C. 103(a) as being unpatentable over Saija et al. as applied to claim 40, 41, 42, 69 and 70 above, and further in view of Yokozawa et al. and Manson et al. and Kitiyakara et al. (AEP, 1995).

The descriptions of claims 40, 41, 42, 69 and 70 are recited in the 35 U.S.C § 103 rejection over Saija et al. above and are applied here as well. Claims 53-55 are to a method that uses the composition of claim 40 to reduce hypertension.

While Saija et al. renders obvious the composition they do not teach that this composition is used to treat hypertension. Regardless this would be obvious to one of ordinary skill in the art in view of the teachings of Yokozawa et al. in view of those of Manson et al. and Kitiyakara et al. Saija et al. teach that both caffeic acid and ferulic acid are known antioxidants (Saija, Abstract). Yokozawa et al. teach that the antioxidant caffeic acid or its derivatives alone can reduce hypertension via a reduction in systolic and diastolic blood pressures (Yokozawa, Table 1). Manson et al. teach that dietary antioxidants in general reduce hypertension (Manson, pg 262, col 1, Antiatherogenic Effects of Antioxidant Vitamins). Indeed Kitiyakara et al. supports the teachings of Manson et al. by showing a wide range of antioxidants of varying size and structure and mechanisms are useful for treating hypertension (Kitiyakara, Table 1). Therefore one of ordinary skill in the art would think it obvious to apply the antioxidant composition of Saija et al. of caffeic and ferulic acid to treat hypertension in view of the art that shows antioxidants including caffeic acid alone are useful for such a purpose.

Therefore these references render obvious claims 40, 41, 42, 53-55, 69 and 70.

No claims are currently allowed in this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1651

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/

Primary Examiner, Art Unit 1651

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Art Unit 1651

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Primary Examiner
Art Unit 1651

Application/Control Number: 09/922,694
Art Unit: 1651

Page 10